

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION**

**IN RE: DIGITEK PRODUCT LIABILITY
LITIGATION**

MDL NO. 1968

THIS DOCUMENT RELATES TO ALL CASES

**MEMORANDUM IN SUPPORT OF MOTION TO DISMISS
COUNT EIGHTEEN OF THE
MASTER CONSOLIDATED COMPLAINT FOR INDIVIDUALS**

I. INTRODUCTION

This action arises out of Plaintiffs' various state and federal law claims against the Defendants relating to the manufacture and distribution of the prescription medicine Digitek®. Count Eighteen, titled Medicare Secondary Payer Act, is a claim for "double damages" by those Plaintiffs whose alleged medical care costs arising from the ingestion of Digitek® were paid in whole or part by Medicare. This subgroup of Plaintiffs alleges a private cause of action under the "Enforcement" section of the Medicare as Secondary Payer Act ("MSP"). *See* 42 U.S.C. §1395y(b)(3)(A). Plaintiffs, however, cannot state a private cause of action under the MSP because: (1) they fail to allege that the Defendants are a "primary plan" under the MSP; and (2) even if they had, Defendants – alleged tortfeasors – have no responsibility to reimburse any Medicare payments.

II. FACTS PERTINENT TO THIS MOTION TO DISMISS

Plaintiffs filed the Master Complaint (ECF No. 73) on February 9, 2009. In Count Eighteen, they aver that those Plaintiffs who received Medicare payments for their alleged injuries from the ingestion of Digitek® are entitled to “double damages” under a private right of action for those payments. Plaintiffs’ Count Eighteen states, in its entirety:

In addition to their own personal injury claims, Plaintiffs, whose medical care costs arising from Digitek® (Digoxin) were paid in whole or part by Medicare, bring this cause of action pursuant to the private cause of action provisions of the Medicare as Secondary Payer Statute [42 U.S.C. § 1395y(b)(3)(A)] to recover “double damages” of all Medicare expenditures resulting from their injuries suffered in connection with the recalled Digitek® (Digoxin).

That is, Plaintiffs seek damages in double the amount of Medicare payments made to them for any injury allegedly caused by their ingestion of Digitek®. Notably absent from Count Eighteen is any allegation that Defendants are a “primary plan” under the MSP, or how the Defendants, as alleged tortfeasors, are responsible for reimbursing Medicare for these payments.

III. LAW AND ARGUMENT

A. Medicare as Secondary Payer Act

The MSP is an attempt by Congress to bring money back into the Medicare system. It consists of a series of amendments to the Medicare Act that are “designed to ‘reduce Medicare costs by making the government a secondary provider of medical insurance coverage when a Medicare recipient has other sources of primary insurance coverage.’” *See Brown v. Thompson*, 374 F.3d 253, 257 (4th Cir. 2004) (quoting *Thompson v. Goetzmann*, 337 F.3d 489, 495 (5th Cir. 2003)). The Act’s purpose is straight forward – require that primary insurers pay medical bills they are required to pay before Medicare pays them, and if Medicare is forced to pay, provide a

legal mechanism for reimbursing those payments. *See Fanning v. The United States*, 346 F.3d 386, 388-90 (3d Cir. 2003).

1. **When are “primary plans” required to reimburse Medicare?**

Primary plans¹ are obligated to reimburse Medicare when it is “demonstrated” that the plan “has or had a responsibility” for the payments “with respect to such item or service.” The MSP provides as follows:

A primary plan, and an entity that receives payment from a primary plan shall reimburse the appropriate Trust Fund for any payment made by the Secretary... if it is demonstrated that such primary plan has or had a responsibility to make payment with respect to such item or service.

42 U.S.C. § 1395y(b)(2)(B)(ii). The MSP provides the “means” for “demonstrating” a primary plan’s obligation to pay:

A primary plan’s responsibility for such payment may be demonstrated by a judgment, a payment conditioned upon the recipient’s compromise, waiver, or release (whether or not there is a determination or admission of liability) of payment for items or services included in a claim against the primary plan or the primary plan’s insured, or by other means.

42 U.S.C. § 1395y(b)(2)(B)(ii). An adjudication of liability is not required – a settlement under the MSP is sufficient to establish a primary plan’s obligation to reimburse Medicare.

2. **When is a private cause of action available to seek reimbursement of Medicare?**

The MSP creates a private cause of action to enforce the terms of its payment obligations. The enforcement provision provides, in its entirety, as follows:

¹ This Motion does not address whether Defendants are actually a “primary plan” under the MSP because Plaintiffs fail to even mention the Defendants in Count Eighteen.

There is established a private cause of action for damages (which shall be in an amount double the amount otherwise provided) in the case of a primary plan which fails to provide for primary payment (or appropriate reimbursement) in accordance with paragraphs (1) and (2)(A).

42 U.S.C. § 1395y(b)(3)(A). A private cause of action provides for damages in an amount double the Medicare payments for the primary plan's failure to reimburse Medicare.

B. Plaintiffs Cannot State a Valid Private Cause of Action Against Alleged Tortfeasors Under the Medicare as Secondary Payer Act.

Rule 12(b)(6) requires dismissal of a cause of action that fails to state a claim upon which relief can be granted. Fed. R. Civ. P. 12(b)(6). Although a trial court ruling on a Motion to Dismiss under Rule 12(b)(6) generally must "take the facts in the light most favorable to the plaintiff," this Court "need not accept the legal conclusions drawn from the facts." *Giarratano v. Johnson*, 521 F.3d 298, 302 (4th Cir. 2008) (quoting *Eastern Shore Mkts., Inc. v. J.D. Assocs. Ltd. P'ship*, 213 F.3d 175, 180 (4th Cir. 2000)). Unsupported conclusory statements are not considered admitted for purposes of a motion to dismiss and are insufficient to withstand such a motion. *Eastern*, 213 F.3d at 180.

"Considering the provisions of the MSP together, there are three elements of MSP's private cause of action: (1) a primary plan; (2) that is responsible to pay for an item or service; and (3) that failed to make the appropriate payment to Medicare for the item or service." *Glover v. Phillip Morris USA*, 380 F. Supp. 2d 1279, 1290 (M.D.Fl. 2005). Plaintiffs' MSP claim should be dismissed because Plaintiffs fail to allege that Defendants are a "primary plan," and cannot allege that Defendants, alleged tortfeasors, are responsible for reimbursing Medicare, let alone aver that they failed to do so.

As to the first element, Plaintiffs' MSP claim should be dismissed because they fail to allege that Defendants are a "primary plan" required to reimburse Medicare under the MSP. Indeed, Plaintiffs do not even mention the Defendants in Count Eighteen of the Master Complaint. Instead, Plaintiffs merely make a conclusory allegation that they are entitled to "double damages" for "all Medicare expenditures resulting from their injuries suffered in connection with the recalled Digitek® (Digoxin)." Count Eighteen should be dismissed on this ground alone.

As to the second and third elements, Plaintiffs cannot state a valid claim under the MSP against Defendants, as alleged tortfeasors, for failure to reimburse Medicare because Plaintiffs can neither "demonstrate[]" that it is the Defendants "responsibility" to reimburse Medicare, nor that the Defendants refused to pay as required under the MSP. *See* 42 U.S.C. § 1395y(b)(2)(B)(ii). The MSP requires a primary plan to reimburse Medicare only "if it is demonstrated" under the MSP that the primary plan "has or had a responsibility" to make the payment. *See* 42 U.S.C. § 1395y(b)(2)(B)(ii). Conducting this same analysis, the Court in *Glover v. Phillip Morris USA* concluded, "[a]pplying this language it cannot be 'demonstrated' that an alleged tortfeasor, which has neither been adjudicated as liable nor has agreed to settle a tort claim, 'has' an existing 'responsibility' to reimburse Medicare or 'had' a previous responsibility to do so." *Glover*, 380 F. Supp. 2d at 1290.

The issue presented is one of timing – specifically, must a plan's financial 'responsibility' to Medicare be fully established before the MSP suit may be commenced (or, in 12(b)(6) terms, before a valid MSP claim can be stated), or may a plaintiff instead seek to establish that responsibility by litigating it within the MSP suit?" *Nat'l Comm. To Preserve Social Security*

and Medicare v. Phillip Morris USA, Inc., ---F.Supp.2d---, 2009 WL 590573 (E.D.N.Y. 2009). In a decision issued last month, the court in *National Committee to Preserve Social Security and Medicare* noted that *all* federal courts that have considered this question have concluded that a responsibility to pay must be established before suit can be brought under the MSP. *Id.* at *4 (citing *Mason v. American Tobacco*, 346 F.3d 36, 43 (2d Cir. 2003) (holding that “defendants are clearly correct when they assert that the ‘trigger for bringing a MSP claim is not the pendency of a disputed tort claim, but the established obligation to pay medical costs pursuant to a pre-existing arrangement to provide insurance benefits.’”); *Glover v. Liggett Group, Inc.*, 459 F.3d 1304, 1309 (11th Cir. 2006) (“we conclude that an alleged tortfeasor’s responsibility for payment of a Medicare beneficiary’s medical costs must be demonstrated *before* an MSP private cause of action for failure to reimburse Medicare can correctly be brought under section 1395y(b)(3)(A)” (emphasis in original)); *see also Glover v. Philip Morris USA*, 380 F.Supp.2d at 1295 (holding that the MSP “simply does not support plaintiffs’ private cause of action where the underlying tort liability is unresolved and defendants’ responsibility to pay Medicare has not been established...”).

Here, Plaintiffs cannot “demonstrate” that Defendants have a “responsibility” to reimburse Medicare. There has been neither an adjudication of liability nor a settlement. Given the procedural posture of this case, Plaintiffs cannot allege the basic elements of a private cause of action under the MSP and Count Eighteen should be dismissed.


IV. CONCLUSION

In sum, Plaintiffs cannot allege the basic elements of a private cause of action under the MSP, because Plaintiffs (1) have failed to aver that the Defendants are a “primary plan,” and (2)

cannot demonstrate that Defendants, as alleged tortfeasors, have a responsibility for any Medicare payments to the Plaintiffs. Therefore, this Court should dismiss Count Eighteen: Medicare Secondary Payer Act of Plaintiffs' Master Consolidated Complaint for Individuals.

ALLEN GUTHRIE & THOMAS, PLLC

TUCKER ELLIS & WEST LLP

By: 
Rebecca A. Betts (WV Bar #329),
LIAISON COUNSEL
500 Lee Street East, Suite 800
Charleston, West Virginia 25301
Tel: (304) 345-7250
Fax: (304) 345-9941
E-mail: rabetts@agmtlaw.com
Attorney for Defendants

By: /s/ Richard A. Dean
Richard A. Dean (Ohio Bar #0013165),
CO-LEAD COUNSEL
Matthew P. Moriarty (WV Bar # 4571;
Ohio Bar 0028389),
CO-LEAD COUNSEL
Kristen L. Mayer (Ohio Bar #0055505)
925 Euclid Avenue, Suite 1150
Cleveland, Oh 44115-1414
Tel: (216) 592-5000
Fax: (216) 592-5009
E-mail: richard.dean@tuckerellis.com
matthew.moriarty@tuckerellis.com
kristen.mayer@tuckerellis.com

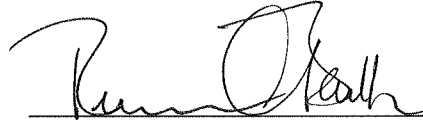
SHOOK, HARDY & BACON LLP

By: /s/ Harvey L. Kaplan
Harvey L. Kaplan
(Missouri Bar # 20459)
CO-LEAD COUNSEL
Madeleine M. McDonough
(Missouri Bar No. 41027)
CO-LEAD COUNSEL
2555 Grand Boulevard
Kansas City, Mo. 64108-2613
Tel: (816) 474-6550
Fax: (816) 421-5547
E-mail: hkaplan@sgb.com
mmdonough@shb.com
*Attorneys for Mylan Pharmaceuticals
Inc., Mylan Bertek Pharmaceuticals
Inc., and UDL Laboratories, Inc.*

*Attorneys for Defendants Actavis Totowa
LLC, Actavis Inc., Actavis Elizabeth LLC,
Mylan Inc.,*

CERTIFICATE OF SERVICE

I hereby certify that on April 20, 2009, I electronically filed the foregoing "Memorandum in Support of the Motion to Dismiss Count Eighteen of the Master Consolidated Complaint for Individuals" with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to all counsel of record.

A handwritten signature in black ink, appearing to read "Rebecca A. Betts", is written over a horizontal line.

REBECCA A. BETTS (WVSB # 329)

ALLEN GUTHRIE & THOMAS, PLLC

500 Lee Street East, Suite 800

P. O. Box 3394

Charleston, WV 25333-3394

(304) 345-7250

(304) 345-9941